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9 INTUITIVE SURGICAL, INC.

10
11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA

13 CHARLES COSBY, MIRNA COSBY,) Case No.: 4:14-CV-00293-JSW
14 RENATA PAGE, LARRY SHARBONDA,)
15 GERALYN SPAROUGH, J. THOMAS)
16 SPAROUGH, TINA TUTTLE,)
17) DEFENDANT INTUITIVE SURGICAL,
18) INC.'S ANSWER AND AFFIRMATIVE
19) DEFENSES TO PLAINTIFFS' COMPLAINT
20) AND DEMAND FOR JURY TRIAL
21)
22)
23)
24)
25)
26)
27)
28)
Plaintiffs,
v.
INTUITIVE SURGICAL, INC.,
Defendant.

17
18 Defendant Intuitive Surgical, Inc. ("Intuitive Surgical" or "Defendant") hereby sets forth
19 the following Answer and Affirmative Defenses to the Complaint ("Complaint") filed by Plaintiffs
20 Charles Cosby, Mirna Cosby, Renata Page, Larry Sharbonda, Geralyn Sparough, J. Thomas
21 Sparough and Tina Tuttle (collectively, "Plaintiffs"), and demands trial by jury. Any allegation,
22 averment, contention or statement in the Complaint not specifically and unequivocally admitted is
23 denied. Intuitive Surgical responds to each of the paragraphs of the Complaint as follows:

24 **RESPONSE TO "COMPLAINT"**

25 The first unnumbered paragraph of the Complaint does not set forth any allegation
26 susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is
27 deemed necessary, Intuitive Surgical incorporates by reference its responses to paragraphs 1
28 through 104 of the Complaint, as set forth below.

RESPONSE TO “THE PARTIES”

1
2 1. Intuitive Surgical is without knowledge or information sufficient to form a belief as
3 to the truth of the allegations of paragraph 1 of the Complaint and for that reason denies each of
4 them.

5 2. Intuitive Surgical is without knowledge or information sufficient to form a belief as
6 to the truth of the allegations of paragraph 2 of the Complaint and for that reason denies each of
7 them.

8 3. Intuitive Surgical is without knowledge or information sufficient to form a belief as
9 to the truth of the allegations of paragraph 3 of the Complaint and for that reason denies each of
10 them.

11 4. Intuitive Surgical is without knowledge or information sufficient to form a belief as
12 to the truth of the allegations of paragraph 4 of the Complaint and for that reason denies each of
13 them.

14 5. Intuitive Surgical is without knowledge or information sufficient to form a belief as
15 to the truth of the allegations of paragraph 5 of the Complaint and for that reason denies each of
16 them.

17 6. Paragraph 6 is denied, except that Intuitive Surgical admits only that it is a
18 Delaware corporation and that its principal place of business is in California.

RESPONSE TO “JURISDICTION AND VENUE”

19
20 7. Paragraph 7 of the Complaint states legal conclusions as to which no responsive
21 pleading is required. To the extent a response is deemed necessary, Intuitive Surgical states that,
22 upon information and belief, the parties are diverse and the amount in controversy exceeds the sum
23 of \$75,000, exclusive of interest and costs.

RESPONSE TO “GENERAL ALLEGATIONS”

24
25 8. Intuitive Surgical is without knowledge or information sufficient to form a belief as
26 to the truth of the allegations of paragraph 8 of the Complaint and for that reason denies each of
27 them.

28 9. Intuitive Surgical is without knowledge or information sufficient to form a belief as

1 to the truth of the allegations of paragraph 9 of the Complaint and for that reason denies each of
2 them.

3 10. Intuitive Surgical is without knowledge or information sufficient to form a belief as
4 to the truth of the allegations of paragraph 10 of the Complaint and for that reason denies each of
5 them.

6 11. Intuitive Surgical is without knowledge or information sufficient to form a belief as
7 to the truth of the allegations of paragraph 11 of the Complaint and for that reason denies each of
8 them.

9 12. Paragraph 12 is denied, except that Intuitive Surgical admits only that it is a publicly
10 traded company on the NASDAQ exchange. Furthermore, Intuitive Surgical states that paragraph
11 12 of the Complaint paraphrases and characterizes information regarding Intuitive Surgical's
12 current market value, which is publicly available information that speaks for itself and Plaintiffs'
13 attempt to paraphrase or characterize the information is denied.

14 13. Paragraph 13 is denied, except that Intuitive Surgical admits only that it has
15 manufactured, designed, tested, sold, promoted, and labeled the *da Vinci* Surgical System.

16 14. Paragraph 14 is denied except Intuitive Surgical admits only that paragraph 14
17 purports to allege particular contents of Intuitive Surgical's website.

18 15. Paragraph 15 is denied, except that Intuitive Surgical admits only that the *da Vinci*
19 Surgical System is used in hospitals for a variety of surgeries, including gynecological, and
20 including therein, hysterectomies.

21 16. Intuitive Surgical admits only that it made those representations contained in its
22 marketing and promotional materials for the *da Vinci* Surgical System and those representations
23 accurately presented the risks and benefits of the system. Intuitive Surgical denies all remaining
24 allegations in paragraph 16 of the Complaint.

25 17. Intuitive Surgical denies each allegation of paragraph 17 of the Complaint.

26 18. Intuitive Surgical denies each allegation of paragraph 18 of the Complaint.

27 19. Intuitive Surgical denies each allegation of paragraph 19 of the Complaint.

28 20. Intuitive Surgical denies each allegation of paragraph 20 of the Complaint.

- 1 21. Intuitive Surgical denies each allegation of paragraph 21 of the Complaint.
- 2 22. Intuitive Surgical denies each allegation of paragraph 22 of the Complaint.
- 3 23. Intuitive Surgical denies each allegation of paragraph 23 of the Complaint.
- 4 24. Intuitive Surgical denies each allegation of paragraph 24 of the Complaint.
- 5 25. Intuitive Surgical denies each allegation of paragraph 25 of the Complaint.
- 6 26. Intuitive Surgical denies each allegation of paragraph 26 of the Complaint.
- 7 27. Intuitive Surgical denies each allegation of paragraph 27 of the Complaint.
- 8 28. Intuitive Surgical denies each allegation of paragraph 28 of the Complaint.
- 9 29. Intuitive Surgical denies each allegation of paragraph 29 of the Complaint.
- 10 30. Intuitive Surgical denies each allegation of paragraph 30 of the Complaint.
- 11 31. Intuitive Surgical denies each allegation of paragraph 31 of the Complaint.
- 12 32. Intuitive Surgical denies each allegation of paragraph 32 of the Complaint.
- 13 33. Intuitive Surgical denies each allegation of paragraph 33 of the Complaint.
- 14 34. Intuitive Surgical denies each allegation of paragraph 34 of the Complaint.
- 15 35. Intuitive Surgical denies each allegation of paragraph 35 of the Complaint.
- 16 36. Intuitive Surgical denies each allegation of paragraph 36 of the Complaint.
- 17 37. Intuitive Surgical denies each allegation of paragraph 37 of the Complaint.
- 18 38. Intuitive Surgical denies each allegation of paragraph 38 of the Complaint.
- 19 39. Intuitive Surgical denies each allegation of paragraph 39 of the Complaint.
- 20 40. Intuitive Surgical denies each allegation of paragraph 40 of the Complaint.
- 21 41. Intuitive Surgical denies each allegation of paragraph 41 of the Complaint.
- 22 42. Intuitive Surgical denies each allegation of paragraph 42 of the Complaint.

23 **RESPONSE TO “FIRST CAUSE OF ACTION - PRODUCT LIABILITY”**

24 43. Intuitive Surgical restates and incorporates by reference each of the preceding
25 paragraphs of this Answer.

26 44. Intuitive Surgical denies each allegation of paragraph 44 of the Complaint.

27 45. Paragraph 45 of the Complaint states legal conclusions to which no responsive
28 pleading is required. To the extent a response is deemed necessary, paragraph 45 is denied except

Intuitive Surgical admits such duties and obligations as are imposed by applicable law, and denies any violation of said duties and obligations.

46. Paragraph 46 of the Complaint states legal conclusions to which no responsive pleading is required. To the extent a response is deemed necessary, paragraph 46 is denied except Intuitive Surgical admits such duties and obligations as are imposed by applicable law, and denies any violation of said duties and obligations.

47. Intuitive Surgical denies each allegation of paragraph 47 of the Complaint, including each subpart.

48. Intuitive Surgical denies each allegation of paragraph 48 of the Complaint.

49. Intuitive Surgical denies each allegation of paragraph 49 of the Complaint.

50. Intuitive Surgical denies each allegation of paragraph 50 of the Complaint.

51. Intuitive Surgical denies each allegation of paragraph 51 of the Complaint.

52. Intuitive Surgical admits only that it designed, tested, inspected, manufactured, packaged, marketed, distributed, promoted, and sold the *da Vinci* Surgical System.

53. Intuitive Surgical denies each allegation of paragraph 53 of the Complaint.

54. Intuitive Surgical denies each allegation of paragraph 54 of the Complaint.

55. Intuitive Surgical is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 55 of the Complaint and for that reason denies each of them.

56. Intuitive Surgical denies each allegation of paragraph 56 of the Complaint.

57. Intuitive Surgical denies each allegation of paragraph 57 of the Complaint.

58. Intuitive Surgical denies each allegation of paragraph 58 of the Complaint.

59. Intuitive Surgical denies each allegation of paragraph 59 of the Complaint.

60. Intuitive Surgical denies each allegation of paragraph 60 of the Complaint.

61. Intuitive Surgical denies each allegation of paragraph 61 of the Complaint.

62. Intuitive Surgical denies each allegation of paragraph 62 of the Complaint.

63. Intuitive Surgical denies each allegation of paragraph 63 of the Complaint.

64. Intuitive Surgical denies each allegation of paragraph 64 of the Complaint.

1 65. Intuitive Surgical denies each allegation of paragraph 65 of the Complaint.

2 66. Intuitive Surgical denies each allegation of paragraph 66 of the Complaint.

3 67. Intuitive Surgical denies each allegation of paragraph 67 of the Complaint.

4 68. Intuitive Surgical denies each allegation of paragraph 68 of the Complaint.

5 69. Intuitive Surgical denies each allegation of paragraph 69 of the Complaint.

6 70. Intuitive Surgical denies each allegation of paragraph 70 of the Complaint.

7 71. Intuitive Surgical denies each allegation of paragraph 71 of the Complaint.

8 Responding to the unnumbered WHEREFORE paragraph following paragraph 71 of
9 the Complaint, Intuitive Surgical admits that Plaintiffs seeks the relief set forth therein, but denies
10 that Plaintiffs are entitled to such relief, or to any relief whatsoever.

11 **RESPONSE TO “SECOND CAUSE OF ACTION – GENERAL NEGLIGENCE &**
12 **NEGLIGENT TRAINING & PROCTORING & NEGLIGENT CERTIFICATION”**

13 72. Intuitive Surgical restates and incorporates by reference each of the preceding
14 paragraphs of this Answer.

15 73. Intuitive Surgical denies each allegation of paragraph 73 of the Complaint.

16 74. Intuitive Surgical denies each allegation of paragraph 74 of the Complaint.

17 75. Intuitive Surgical denies each allegation of paragraph 75 of the Complaint.

18 76. Intuitive Surgical denies each allegation of paragraph 76 of the Complaint.

19 77. Intuitive Surgical denies each allegation of paragraph 77 of the Complaint.

20 **RESPONSE TO “THIRD CAUSE OF ACTION –**
21 **BREACH OF EXPRESS WARRANTY”**

22 78. Intuitive Surgical restates and incorporates by reference each of the preceding
23 paragraphs of this Answer.

24 79. Paragraph 79 of the Complaint states legal conclusions as to which no responsive
25 pleading is required. To the extent a response is deemed necessary, Paragraph 79 is denied.

26 80. Intuitive Surgical denies each allegation of paragraph 80 of the Complaint,
27 including each subpart.

28 81. Intuitive Surgical denies each allegation of paragraph 81 of the Complaint.

82. Intuitive Surgical denies each allegation of paragraph 82 of the Complaint.

83. Intuitive Surgical denies each allegation of paragraph 83 of the Complaint.

84. Intuitive Surgical denies each allegation of paragraph 84 of the Complaint and denies that this lawsuit constitutes adequate notice of any alleged breach of express warranty.

85. Intuitive Surgical denies each allegation of paragraph 85 of the Complaint.

86. Intuitive Surgical denies each allegation of paragraph 86 of the Complaint.

87. Intuitive Surgical denies each allegation of paragraph 87 of the Complaint.

Responding to the unnumbered WHEREFORE paragraph following paragraph 87 of the Complaint, Intuitive Surgical admits that Plaintiffs seek the relief set forth therein, but denies that Plaintiffs are entitled to such relief, or to any relief whatsoever.

**RESPONSE TO “FOURTH CAUSE OF ACTION –
BREACH OF IMPLIED WARRANTY”**

88. Intuitive Surgical restates and incorporates by reference each of the preceding paragraphs of this Answer.

89. Paragraph 89 is denied, except Intuitive Surgical admits only that it has manufactured, distributed, advertised, promoted, and sold the *da Vinci* Surgical System.

90. Paragraph 90 of the Complaint states legal conclusions as to which no responsive pleading is required. To the extent a response is deemed necessary, Paragraph 90 is denied except Intuitive Surgical admits only those implied warranties imposed by applicable law, and denies any violation of said warranties.

91. Intuitive Surgical denies each allegation of paragraph 91 of the Complaint, including each subpart, except Intuitive Surgical admits only those implied warranties imposed by applicable law.

92. Intuitive Surgical denies each allegation of paragraph 92 of the Complaint.

93. Intuitive Surgical denies each allegation of paragraph 93 of the Complaint.

94. Intuitive Surgical denies each allegation of paragraph 94 of the Complaint.

95. Intuitive Surgical denies each allegation of paragraph 95 of the Complaint.

Responding to the unnumbered WHEREFORE paragraph following paragraph 95 of

1 the Complaint, Intuitive Surgical admits that Plaintiffs seek the relief set forth therein, but denies
2 that Plaintiffs are entitled to such relief, or to any relief whatsoever.

3 **RESPONSE TO “FIFTH CAUSE OF ACTION –**
4 **UNJUST ENRICHMENT”**

5 96. Intuitive Surgical restates and incorporates by reference each of the preceding
6 paragraphs of this Answer.

7 97. Intuitive Surgical admits that it has designed, advertised, marketed, promoted,
8 manufactured, distributed, and sold the *da Vinci* Surgical System.

9 98. Intuitive Surgical is without knowledge or information sufficient to form a belief as
10 to the truth of the allegations of paragraph 98 of the Complaint and for that reason denies each of
11 them.

12 99. Intuitive Surgical is without knowledge or information sufficient to form a belief as
13 to the truth of the allegations of paragraph 99 of the Complaint and for that reason denies each of
14 them.

15 100. Intuitive Surgical denies each allegation of paragraph 100 of the Complaint.

16 101. Intuitive Surgical denies each allegation of paragraph 101 of the Complaint.

17 Responding to the unnumbered WHEREFORE paragraph following paragraph 101
18 of the Complaint, Intuitive Surgical admits that Plaintiffs seek the relief set forth therein, but denies
19 that Plaintiffs are entitled to such relief, or to any relief whatsoever.

20 **RESPONSE TO “SIXTH CAUSE OF ACTION –**
21 **LOSS OF CONSORTIUM”**

22 102. Intuitive Surgical restates and incorporates by reference each of the preceding
23 paragraphs of this Answer.

24 103. Intuitive Surgical denies each allegation of paragraph 103 of the Complaint.

25 104. Intuitive Surgical denies each allegation of paragraph 104 of the Complaint.

26 Responding to the unnumbered WHEREFORE paragraph following paragraph 104
27 of the Complaint, Intuitive Surgical admits that Plaintiffs seek the relief set forth therein, but denies
28 that Plaintiffs are entitled to such relief, or to any relief whatsoever.

1 **RESPONSE TO “DEMAND FOR JURY TRIAL”**

2 The unnumbered paragraph following the heading “DEMAND FOR JURY TRIAL”
3 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is
4 required.

5 **RESPONSE TO “GLOBAL PRAYER FOR RELIEF”**

6 Responding to the unnumbered paragraph following the heading “GLOBAL
7 PRAYER FOR RELIEF,” including each numbered subpart, Intuitive Surgical denies that its
8 conduct or the *da Vinci* Surgical System caused or contributed to Plaintiffs’ alleged injuries and
9 denies that it is liable to Plaintiffs for damages or any other relief sought in the Complaint, or any
10 relief whatsoever.

11 **AFFIRMATIVE DEFENSES**

12 By asserting the following affirmative defenses, Intuitive Surgical does not allege or admit
13 it has the burden of proof or the burden of persuasion with respect to any of these matters:

14 **First Defense**

15 Plaintiffs’ Complaint fails to state a claim against Intuitive Surgical upon which relief may
16 be granted.

17 **Second Defense**

18 Venue may be improper and/or inconvenient in this Court.

19 **Third Defense**

20 Intuitive Surgical specifically denies all allegations of duty, breach, negligence, defect,
21 causation, and all forms of damages and demands strict proof thereof.

22 **Fourth Defense**

23 Plaintiffs’ claims may be barred by the doctrine(s) contained in Restatement (Second) of
24 Torts § 402A, Comment k, and/or Restatement (Third) of Torts: Products Liability § 6. The
25 medical device in question is useful and desirable, and any risk claimed by Plaintiffs with their use
26 and the alleged injury, to the extent it exists, is unavoidable.

Fifth Defense

Plaintiffs' claims may be barred, in whole or in part, by misuse or unintended use of the medical device in question.

Sixth Defense

Plaintiffs' claims may be barred, in whole or in part, by the "learned intermediary" or "informed intermediary" doctrine.

Seventh Defense

Plaintiffs' claims may be barred because Plaintiffs' injuries, if any, were actually or proximately caused, in whole or in part, by the intervening or superseding conduct of independent third parties and non-parties to this action or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, or independent of or far removed from Intuitive Surgical's conduct or control.

Eighth Defense

Plaintiffs' claims may be barred, in whole or in part, by the doctrines of informed consent or assumption of risk.

Ninth Defense

Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs' injuries were caused, in whole or in part, by negligence, fault, or wrongful conduct of third parties, and Plaintiffs' claims may be barred or limited by the doctrines of comparative fault or contributory negligence.

Tenth Defense

Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs did not rely to their detriment upon any statement by Intuitive Surgical in electing to undergo surgery that used the *da Vinci* Surgical System.

Eleventh Defense

Plaintiffs' claims may be barred, in whole or in part, by applicable statutes of limitations and/or repose.

Twelfth Defense

Plaintiffs' claims may be barred, in whole or in part, by the doctrines of waiver, laches, or estoppel.

Thirteenth Defense

Plaintiffs' damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiffs as a result of any insurance or other health benefits plan, or any amounts paid by any insurance or other health benefits plan.

Fourteenth Defense

Plaintiffs' claims are barred, in whole or in part, because the medical device at issue was at all relevant times manufactured and sold consistent with available technology, scientific knowledge, and the state of the art, and in compliance with all federal, state, and local laws and regulations, and was accompanied by product information and warnings that were reasonable, full and adequate and in accordance with FDA regulating requirements and the state of medical and scientific knowledge then in existence. Plaintiffs' claims are also barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act ("FDCA") and the Medical Device Amendments thereto.

Fifteenth Defense

Plaintiffs' damages, if any, may be limited, in whole or in part, by Plaintiffs' failure to mitigate.

Sixteenth Defense

Plaintiffs' claims and causes of action are preempted by Medical Device Amendments to the Federal Food, Drug & Cosmetic Act ("FDCA") and the FDA regulations promulgated pursuant thereto. To the extent Plaintiffs' claims are based on alleged violations of the FDCA, such claims are barred pursuant to 21 U.S.C. § 337(a) and *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001). Additionally, Plaintiffs' claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Intuitive Surgical and all its activities with respect to the subject device have been and are conducted under the supervision of the FDA.

1 Seventeenth Defense

2 Intuitive Surgical is entitled to, and claims the benefit of, all defenses and presumptions set
 3 forth in or arising from any rule of law or statute of the States of Arizona, Indiana, New Jersey,
 4 Ohio or any other applicable law.

5 Eighteenth Defense

6 To the extent Plaintiffs seek punitive or exemplary damages against Intuitive Surgical,
 7 unless Intuitive Surgical's liability for punitive damages and the appropriate amount of punitive
 8 damages are required to be established by clear and convincing evidence, any award of punitive
 9 damages would violate Intuitive Surgical's due process rights guaranteed by the Fourteenth
 10 Amendment to the United States Constitution and by the state constitution of any State of the
 11 United States whose laws might be deemed to apply in this case, and would be improper under the
 12 common law and public policies of that state.

13 Nineteenth Defense

14 To the extent Plaintiffs seek punitive or exemplary damages against Intuitive Surgical, any
 15 such claim of Plaintiffs for punitive damages against Intuitive Surgical cannot be maintained,
 16 because an award of punitive damages under applicable law would be unlawful and unauthorized,
 17 and would be void for vagueness, both facially and as applied, as a result of, among other
 18 deficiencies, the absence of adequate notice of what conduct is subject to punishment; the absence
 19 of adequate notice of what punishment may be imposed; and the absence of a predetermined limit,
 20 such as a maximum multiple of compensatory damages or a maximum amount, on the amount of
 21 punitive damages that a jury may impose, all in violation of the due process clause of the
 22 Fourteenth Amendment to the United States Constitution, and by the applicable state constitution,
 23 and the common law and public policies of that state.

24 Twentieth Defense

25 To the extent Plaintiffs seek punitive or exemplary damages against Intuitive Surgical, any
 26 such claim cannot be maintained, because any award of punitive damages under applicable law
 27 would be by a jury that (1) is not provided standards of sufficient clarity for determining the
 28 appropriateness, and the appropriate size, of a punitive damages award, (2) is not adequately

1 instructed on the limits on punitive damages imposed by the applicable principles of deterrence and
 2 punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the
 3 amount of an award of punitive damages, in whole or in part, on the basis of invidiously
 4 discriminatory characteristics, including the residence, wealth, and corporate status of Intuitive
 5 Surgical, (4) is permitted to award punitive damages under a standard for determining liability for
 6 punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct
 7 or mental state that makes punitive damages permissible, (5) is permitted to award punitive
 8 damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that
 9 was not directed, or did not proximately cause harm, if any, to Plaintiff, (6) is permitted to award
 10 punitive damages in an amount that is not both reasonable and proportionate to the amount of
 11 harm, if any, to Plaintiffs and to the amount of compensatory damages, if any, and (7) is not subject
 12 to adequate trial court and appellate judicial review for reasonableness and furtherance of
 13 legitimate purposes on the basis of objective standards. Any such verdict would violate Intuitive
 14 Surgical's due process rights guaranteed by the Fourteenth Amendment to the United States
 15 Constitution and by the due process and equal protection provisions of the constitution of any State
 16 of the United States whose laws might be deemed to apply in this case, and would be improper
 17 under the common law and public policies of that state.

18 **Twenty-First Defense**

19 To the extent Plaintiffs seek to recover punitive or exemplary damages against Intuitive
 20 Surgical, any award of punitive damages based on injuries to individuals that are not parties to this
 21 lawsuit or anything other than Intuitive Surgical's conduct in connection with the design,
 22 manufacture, and sale of the specific medical devices that are the subject of this lawsuit would
 23 violate the due process clause of the Fourteenth Amendment to the United States Constitution and
 24 the due process provisions of the applicable state constitution, and would be improper under the
 25 common law and public policies of that state, because any other judgment for punitive damages in
 26 this case cannot protect Intuitive Surgical against impermissible multiple punishment for the same
 27 wrong and against punishment for extra territorial conduct, including especially conduct that is
 28 lawful in states other than the applicable state. In addition, any such award would violate

principles of comity under the laws of that state.

Twenty-Second Defense

To the extent Plaintiffs seek to recover punitive or exemplary damages against Intuitive Surgical, any such claim of Plaintiffs for punitive damages against Intuitive Surgical cannot be maintained, because an award of punitive damages would be preempted pursuant to 21 U.S.C. § 337(a) and *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), which make clear that the FDA has sole discretion to pursue enforcement remedies against prescription-drug manufacturers.

Twenty-Third Defense

Plaintiffs' claims are barred because of Plaintiffs' failure to join necessary and indispensable parties.

Twenty-Fourth Defense

The claims asserted in the Complaint are barred because the risks, if any, associated with the use of the *da Vinci* Surgical System are outweighed by the device's utility.

Twenty-Fifth Defense

To the extent Plaintiffs' claims relate to Intuitive Surgical's advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitutions of the States of Arizona, Indiana, New Jersey, Ohio, or any other applicable state constitutions, such claims are barred.

Twenty-Sixth Defense

The claims set forth in the Complaint are barred because the alleged injuries and damages, if any, were caused by medical conditions, disease, illness, or processes (whether pre-existing or contemporaneous) unrelated to the *da Vinci* Surgical System.

Twenty-Seventh Defense

Plaintiffs' claims of product defects are barred by Sections 2, 4, and 6(c) and (d) of the Restatement (Third) of Torts: Products Liability.

Intuitive Surgical reserves the right to amend, or to seek leave to amend, its Answer and Affirmative Defenses as its investigation and discovery of the case proceeds.

INTUITIVE SURGICAL'S PRAYER FOR RELIEF

WHEREFORE, Intuitive Surgical prays as follows:

1. That Plaintiffs take nothing by reason of the Complaint, that judgment be rendered in favor of Defendant;
2. That Defendant be awarded its costs of suit incurred in defense of this action; and
3. For such other relief as the Court deems proper.

DATED: May 7, 2014

Respectfully submitted,

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

By: /s/ Allen Ruby
Allen Ruby
Attorney for Defendant
INTUITIVE SURGICAL, INC.

DEMAND FOR JURY TRIAL

Intuitive Surgical hereby demands a trial by jury on all issues so triable.

DATED: May 7, 2014

Respectfully submitted,

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

By: /s/ Allen Ruby
Allen Ruby
Attorney for Defendant
INTUITIVE SURGICAL, INC.